Centers for Medicare & Medicaid Services
Center for Medicare Management
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Application for New Medical Services and Technologies Seeking to Qualify for Add-On Payments Under the Hospital Inpatient Prospective Payment System for Federal Fiscal Year (FY) 2019

Section 1886(d)(5)(K) authorizes the Secretary to establish a special payment methodology for new medical services and technologies used in inpatient procedures. To qualify for additional payments under this provision; a new technology must represent a substantial clinical improvement; data reflecting the cost of new technology must not yet be available in the data used to recalibrate the Medicare severity diagnosis-related groups (MS-DRGs); and the MS-DRG payment rate otherwise applicable to the new technology would be inadequate (see 42 CFR 412.87 (b)).

DEADLINE

Submit an application with a response to each question (see required information below) – **No later than October 20, 2017.** Deadline for supplemental information to be included in the annual IPPS Proposed Rule – **No later than December 22, 2017**

Note: *An application is considered **complete** when all of the information requested above and below has been submitted by the dates specified and when questions related to such information have been answered by the applicant.*

WHERE TO SEND APPLICATIONS

Email an electronic version of the application, tracking form and all relevant material and supporting documentation to NewTech@cms.hhs.gov. Total attachments in one email must not exceed 20 megabytes. If necessary, send multiple emails with attachments less than 20 megabytes. Applicants can also include a complete application package (application, tracking form and all relevant material and supporting documentation) on a USB Drive.

If desired, paper copies of each completed application may be mailed to the following address:

Inpatient PPS New Medical Services and Technologies
Division of Acute Care
Mailstop C4-08-06
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

REQUIRED INFORMATION

Applications must include a response to each question below (may be entered directly onto this form). CMS may request other information in order to evaluate specific requests.

Note: Data provided in this application or in the tracking form may become subject to disclosure. If you are providing data or information that is proprietary or otherwise protected from disclosure under the Trade Secrets Act or Exemption 4 under the Freedom of Information Act, please mark this information as such. CMS will attempt, to the extent allowed by Federal law, to keep this information protected from public view.

Note: *A separate application is required for each distinct item included in a request. For example, if an applicant requests add-on payments for two unique technologies or services, a separate application is required for each technology or service.*

1. A completed tracking form. (A tracking form may be downloaded at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech.html.)

2. Name, address, telephone and email address **of primary and backup** contact for the application. If using a consultant, provide a contact from the manufacturer in addition to the consultant's contact information.

3. Trade/brand name of the new technology.

4. Describe the technology fully in general terminology.

   - What is it? What does it do? How is it used?
   - Also, submit relevant descriptive booklets, brochures, package inserts, as well as copies of published peer-reviewed articles relevant to the new medical services and technologies.)

Newness Criterion

Note: *To qualify for a new technology add-on payment, the technology or service must not be reflected in the data used to establish the Medicare-Severity Diagnosis Related Groups (MS-DRGs).*

CMS recommends that each applicant become familiar with the substantial similarity criteria. A brief description of the substantial similarity criteria can be found in Technical Appendix A. For complete details on substantial similarity, we refer the applicant to the FY 2006 Final Rule (70 FR 47351 through 47352) and the FY 2010 Final Rule (74 FR 43813 through 43814).

5. Date of Food and Drug Administration (FDA) (or expected approval) for the technology, service or drug. Provide a copy of the FDA approval/clearance letter. If approval has not yet been granted, please provide a copy of the approval notice to CMS immediately after it becomes available. List the name and phone number of a contact at the FDA who is knowledgeable about the pre-market approval request for the new technology listed above.

   Note: *Include all types of approvals (i.e. Pre-Market Approval, HDE or HUD approval, expanded access approval) the technology, service or drug received prior to submission of this application and/or is currently seeking. CMS recommends a timeline if the technology, service or drug has received multiple types of approvals from the FDA.*

   Per § 412.87(c) of the regulations, an applicant for new technology add-on payments (NTAP) must receive FDA approval or clearance for its new medical service or technology by July 1 prior to the beginning of the fiscal year (FY) for which the NTAP would be effective.

6. Please describe the (most recent, if applicable) type of application and approval the technology, service or drug has received or is seeking from the FDA (i.e. Pre-Market Approval, HDE or HUD approval, expanded access approval, New Drug Approval).

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7. Was the technology, service of drug available on the market immediately after FDA approval? If not, please provide the date that the medical service or technology came on the market (i.e. first sales or availability) and an explanation and documentation of any delay (i.e. manufacturing issues, shelf life concerns or other reasons).

8. If the technology is a drug, was/is your FDA application considered under Fast Track, Breakthrough Therapy, Accelerated Approval, or Priority Review? Refer to http://www.fda.gov/forconsumers/byaudience/forpatientadvocates/speedingaccesstoimportantnewtherapies/ucm128291.htm for more details.

9. If the technology is a drug, is this a drug that can only be administered orally?

10. If the technology is a drug that can only be administered orally, list the National Drug Code(s) (NDC or NDCs) associated with this drug.

    Note: *If a drug that can only be administered orally were to receive add-on payment status approval, it would need to be distinctly identifiable by an NDC in the MedPAR claims data in order to receive add-on payment.*

11. If the technology is a drug, provide complete dosage information.

12. If the technology is a device, is there an investigational device exemption (IDE) number from the FDA assigned to the device? If yes, please provide this code. Refer to http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/ucm051480.htm for more details.

13. If the technology is a device, what class (I, II, or III) was/is assigned to the device? Refer to http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/overview/default.htm for more details.

14. A) Does the service or technology have an existing International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM/PCS) code?

    Note: *If the technology, device or drug (administered via procedure) were to receive add-on payment status approval, it would need to be distinctly identifiable by ICD-10-CM/PCS procedure code(s) in the MedPAR claims data in order to receive add-on payment. Effective October 1, 2015, FY 2016 ICD-10-CM/PCS was implemented and ICD-9-CM will no longer be maintained. ICD-9-CM codes were translated to ICD-10-CM/PCS codes for payment purposes.*

    B) Does the service or technology have an existing International Classification of Diseases, Tenth Revision, Clinical Modification / Procedure Coding System (ICD-10-CM/PCS) procedure code or is an application pending? Refer to http://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/meetings.html for more details.

15. Has the service or technology received a Healthcare Common Procedure Coding System (HCPCS) code? If yes, when was it approved? What is the code? Refer to http://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/index.html for more information.

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16. Have you submitted an outpatient application for pass-through payments under the Medicare outpatient prospective payment system? If so, please provide the tracking number or, if it was approved, please provide the date of approval. Refer to http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html for more information.

17. If applicable, briefly describe current and/or alternative treatments for the disease or condition that your technology treats or diagnoses. To the extent you believe it is relevant, explain how your technology compares to the substantial similarity criteria in Appendix A.

Cost Criterion

Note: *To qualify for a new technology add-on payment, the technology or service must result in average charges for cases using the technology in excess of the thresholds set out in Table 10 (lesser of 75 percent of the standardized amount increased to reflect the difference between costs and charges or 75 percent of 1 standard deviation beyond the geometric mean standardized charge for all cases in the MS-DRGs to which the new technology is assigned) of the annual IPPS final rule. The most recent version of Table 10 can be downloaded at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech.html*

Cost Information

18. What is the (current and/or anticipated) cost of the technology to the hospital, per patient?

19. Provide a breakdown of how the cost of the technology is calculated:

    (e.g. For drugs, the average dosage or number of units per patient (ml/kg/hr); For devices, a breakdown of the cost of all of the components used per patient, clearly showing which components are the "new" ones).

Charge Information

20. Under the MS-DRG grouper for FY 2018, list the MS-DRGs that the technology currently maps to.

21. Has the applicant made a request for the new technology to map to a new or different MS-DRG(s) for the upcoming fiscal year (2019) than the ones listed in question 20?

22. Using the table as demonstrated in the spreadsheet as a template, show how the standardized charge per case (if applicable, case weighted) exceeds the threshold.

    Note: R*efer to Technical Appendix B for an explanation of how to standardize charges. Refer to the spreadsheet in the application packet how to case weight the average standardize charge per case if multiple MS-DRGs are affected by the technology.*

23. With regard to the spreadsheet in question 22, provide all supporting data used to calculate charges and standardized charges per case involving the new technology (in electronic format).

24. List a step by step explanation how the data and calculations within each column of the spreadsheet was determined. For example, within the explanation applicants must include the

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type of data used to calculate the average standardized charge (i.e. Medicare and/or non-Medicare, number of providers, time period from which data was collected) and/or the inflation factor used to inflate the charges etc... **An application is NOT complete without a complete step by step explanation of the applicants charge methodology.**

25. What is the (current and/or anticipated) charge of the technology by the hospital, per patient? Explain how this was determined.

Miscellaneous

26. What is the anticipated Medicare and Non-Medicare volume of this technology for FY 2018 (October 1, 2017 – September 30, 2018) and projected FY 2019 (October 1, 2018 – September 30, 2019) by MS-DRG (the Medicare and Non-Medicare volume must be listed separately)? Please describe how you arrived at this estimate.

Clinical Improvement Criterion

Note: *A summary on the substantial clinical improvement criteria can be found in Technical Appendix C. Complete information on the substantial clinical improvement criterion can be found in the September 7, 2001 Federal Register (66 FR 46913-14) and in the FY 2010 Final Rule (74 FR 43808-43823). Additionally, the annual final rule of prior years includes CMS's decision making process on each application.*

27. Appendix C has descriptions of the substantial clinical improvement criteria, which are associated with treatments, diagnosis, and clinical outcomes. Using Appendix C: 1) identify how the technology meets the one or all three criteria for substantial clinical improvement over existing technologies; and 2) describe the relevant clinical trial(s) and/or other data used to support the claim for substantial clinical improvement over existing technologies. Additionally, in table format, summarize the supporting information that includes relevant clinical trial(s) or data used to support substantial clinical improvements over existing technologies.

28. Provide an annotated list and copies of published peer-reviewed articles relevant to the new service or technology. In the annotation, please clearly summarize each article, describe the purpose of the article, and the relevance to the technology. Please indicate all literature that is referenced in item #25 above.

    Note: *Indicate if any peer-reviewed articles will be released after submission of this application.*

Technical Appendix A

Substantial Similarity (70 FR 47351 through 47352 and 74 FR 43813 through 43814)

A technology is not "new", if it meets **all** three of the criteria below.

1. Whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome; and

2. Whether a product is assigned to the same or a different DRG); and

3. Whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population

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Technical Appendix B

Standardizing Charges

We standardize charges in order to compare charges equally amongst all hospitals. Standardized charges are charges per case minus the wage index, indirect medical education (IME) and disproportionate share hospital (DSH). The formula below explains how to calculate standardized charges per case.

In order to standardize charges you must obtain hospital specific operating cost-to-charge ratio (CCR), capital CCR, DSH (operating and capital), IME (operating and capital), Wage Index, GAF and COLA.

Note: Use all values (DSH, IME etc…) from the fiscal year that corresponds to the year that the claim(s) is/are being submitted from including the Labor and Non Labor share percentage. Also, different labor and non labor percentages may apply for hospitals with a wage index over or under 1 depending on the fiscal year.

Formulae to Standardize Charges:

Capital Charges

The formula to calculate the Capital Standardized Charge is below.

1. Capital Standardized Charge = ((((Capital CCR/(Capital CCR + Operating CCR)) * Covered Charges) / (1 + Capital IME + Capital DSH)) / GAF) / (1 +(0.3152*(COLA-1)))

Operating Charges

The formula to calculate the operating standardized charge is a two step process; first you must calculate the Adjusted Operating Charge (AOC) then use the calculated AOC to compute the Operating Standardized Charge.

2. Adjusted Operating Charge (AOC) = ((Operating CCR / (Capital CCR + Operating CCR)) * Covered Charges) / (1 + Operating IME + Operating DSH)

   If wage index greater than 1:

   i) Operating Standardized Charge = ((AOC* Labor Share %) / wage index) + ((AOC * Non Labor Share %) / COLA)

   If wage index less than 1:

   ii) Operating Standardized Charge = ((AOC * .62) / wage index) + ((AOC * .38) / COLA)

Total Standardized Charges

The formula to calculate Total Standardized Charges is below

3) Standardize Charges = Capital Standardize Charges + Operating Standardized Charges

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Definition Key

-The Labor share percentages and Non Labor share percentages can be obtained from Table 1A of the annual IPPS final rule.

-COLA is always equal to 1, except for hospitals in Alaska and Hawaii.

-Operating CCR, capital CCR, DSH (operating and capital), IME (operating and capital), Wage Index, GAF and COLA values by provider can be obtained by downloading the Public Use Files at:

http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html or

http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Acute-Inpatient-Files-for-Download.html or

http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Historical-Impact-Files-for-FY-1994-through-Present.html

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Technical Appendix C

For Substantial Clinical Improvement, CMS evaluates a request for add-on payment for a new technology against the following criteria:

1. The technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments.
2. The technology offers the ability to diagnose a medical condition in a patient population where that medical condition is currently undetectable or offers the ability to diagnose a medical condition earlier in a patient population than allowed by currently available methods. There must also be evidence that use of the device to make a diagnosis affects the management of the patient.
3. Use of the technology significantly improves clinical outcomes for a patient population as compared to currently available treatments. Some examples of outcomes that are frequently evaluated in studies of medical devices are the following:

    - Reduced mortality rate with use of the device.
    - Reduced rate of device-related complications.
    - Decreased rate of subsequent diagnostic or therapeutic interventions (for example, due to reduced rate of recurrence of the disease process).
    - Decreased number of future hospitalizations or physician visits.
    - More rapid beneficial resolution of the disease process treatment because of the use of the device.
    - Decreased pain, bleeding, or other quantifiable symptom.
    - Reduced recovery time.